

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)	MAIL STOP RCE
Pierre Tchoreloff et al.)	Group Art Unit: 1637
Application No.: 10/579,045)	Examiner: Michael P Woodward
Filed: August 16, 2007)	Confirmation No.: 5006
For: LOW-DOSE TABLETS HAVING A)	
NETWORK OF POLYMERS)	
)	
)	
)	

**Comments regarding the References Cited in the Rejection of
Japanese Patent Application No. 2006-538898,
a counterpart application of the instant application**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In connection with the filing of the Request for Continued Examination (RCE) along with the Third Information Disclosure Statement (IDS), which contains the English Language Translation of the Rejection of Japanese Patent Application No. 2006-538898, a counterpart application of the instant application, dated April 23, 2010, please find the following remarks concerning the six references cited in the rejection.

REMARKS

The following comments are offered regarding the six references cited in the Rejection of Japanese Patent Application No. 2006-538898, a counterpart application.

Allowed claim 1 recites:

1. Tablets obtained by the direct compression of microgranules which are comprised of:

- a neutral support,
- said neutral support being coated with a polymeric layer comprising at least one pharmaceutically acceptable polymer,
- said polymeric layer being coated with an active layer containing at least one active principle ,

wherein the active principle is located in the active layer but is not in the polymeric layer and the polymeric layer is present between the neutral support and the active layer, and the amount of said at least one active principle is less than 50 mg per tablet.

Reference 1, Japanese Patent Laid-Open Publication No. 2003-518062 (also published as WO 01/45706) relates to a dual-release pharmaceutical composition comprising a low water solubility drug in which the active ingredient is present in two fractions in the composition. The first fraction is an immediate-release fraction and the second fraction is a controlled-release, slow-release, programmed-release, timed-release, pulse-release, sustained-release or extended-release fraction. The Japanese Office Action states in relevant part:

B. Reasons 2 and 3/ Claims 1 to 36/ Citations 1 to 4

Citation 1 discloses beads prepared by applying a drug suspension comprising celecoxib and povidone to sugar spheres (neutral support), then applying, to the coated sugar spheres, a polymer coating comprising an aqueous suspension of ethyl cellulose and hydroxypropyl cellulose to form sustained-release beads, and further applying, to the sustained-release beads, a suspension of celecoxib, povidone and croscarmellose sodium. Citation 1 also discloses, for example, that granules are compressed into a

Based on this information in the Japanese Office Action, the composition would have the following structure:

Neutral Support - Active Ingredient - Polymer Layer - Active Ingredient

Reference 2, Japanese Patent Laid-Open Publication No. 2002-516166 (also published as WO 99/61006) relates to a process and apparatus for applying a layer to a pharmaceutical composition. The Japanese Office Action cites this reference for teaching that "it was known in the art to use xanthan gum, gelatin or the like, similarly to hydroxypropyl cellulose, in a controlled-release coating provided on drug-loaded pellets."

Reference 3, Japanese Patent Laid-Open Publication No. 2001-199878 (also published as US Patent No. 6,780,436) relates to a pharmaceutical formulation consisting of a number of pellets that comprise an inert nucleus, a layer with the active ingredient, one or more intermediate layers that comprise at least a system of modified release, and an external layer of enteric coating. Based on information in the reference, the composition would have the following structure:

Inert nucleus - Active Ingredient Layer- Intermediate Layer(s) - Enteric coating Layer

The Japanese Office Action cites this reference for teaching that "microspheres comprising a mixture of sucrose and corn starch and having an average size ranging from 0.3 mm to 1.4 mm are known as a neutral support for coating a drug."

Reference 4, WO 03/090724 (shown below from the English counterpart US 2005/0152976) teaches:

[0018] It follows therefrom that the sustained-release coated particles in accordance with the invention, which comprise

[0019] a core comprising an active principle and at least one binder, and

[0020] a coating film based on at least one cellulose-based polymer, alone or as a mixture with a plasticizer, are characterized in that they comprise a protective coating based on at least one thermoplastic agent with a melting point of from about 25° C. to about 100° C. and which is applied to the coating film based on at least one cellulose-based polymer.

Reference 5, Japanese Patent Laid-Open Publication No. 109414/1983 does not have an English language equivalent and only the abstract provided is available in English.

Reference 6, JP 01-091757 recites in the Abstract :

(54) GRANULE CONTAINING GANODERMA LUCIDUM

(57)Abstract:

PURPOSE: To obtain the titled granule capable of simultaneously providing vitamin C and essence of Ganoderma lucidum, consisting of the core part having a composition comprising a saccharide, the first layer having a composition vitamin C, the saccharide and a binder and the second layer having a composition comprising concentrated Ganoderma lucidum, the saccharide and the binder.

CONSTITUTION: The aimed granule consisting of the core part having a composition comprising a saccharide (preferably monosaccharide, disaccharide or polysaccharide) or the saccharide and a binder, the first layer from the core part, having a composition comprising vitamin C, the saccharide and the binder and the second layer from the core part, having a composition comprising concentrated Ganoderma lucidum or essence of Ganoderma lucidum, the saccharide and the binder.

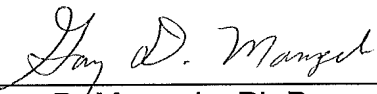
From the foregoing, Applicants earnestly solicit further and favorable action in the form of a Notice of Allowance.

If there are any questions concerning this paper or the application in general, Applicants invite the Examiner to telephone the undersigned at the Examiner's earliest convenience.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: January 12, 2011

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